UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA	§	
	§	
v.	§	**CRIMINAL CASE NO. 3:15-CR-0496-L**
	§	
USPLABS, LLC (01)	§	
a Texas Corporation	§	
JACOBO GEISSLER (02)	§	
also known as Jacob Geissler	§	
JONATHAN DOYLE (03)	§	
MATTHEW HEBERT (04)	§	
KENNETH MILES (5)	§	
S. K. LABORATORIES, INC. (06)	§	
a California Corporation	§	
SITESH PATEL (07)	§	
CYRIL WILLSON (08)	§	
also known as Erik White	§	

AMENDED FINDINGS, CONCLUSIONS, AND RECOMMENDATION OF THE UNITED STATES MAGISTRATE JUDGE

Pursuant to the referrals of District Judge Sam A. Lindsay, the following motions are before the Court for a recommended disposition:

1. *Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Kenneth Miles' Motion to Dismiss Counts Nine and Ten for Unconstitutional Vagueness*, Doc. 221;

2. *Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, Kenneth Miles, S.K. Laboratories, Inc., and Sitesh Patel's Motion to Dismiss Count Ten*, Doc. 220;

3. *Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motion to Dismiss Counts Two Through Four of the First Superseding Indictment as Untimely*, Doc. 293;

4. *Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel and Cyril Willson's Motion to Dismiss Count 7*, Doc. 379;

5. *Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel and Kenneth Miles' Joint Motion to Dismiss Counts 5, 8, and 9*, Doc. 383;

6. *Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motion to Dismiss Count 6*, Doc. 387;

7. *Defendant Kenneth Miles' Motion to Dismiss Count Nine and Ten*, Doc. 392;

8. *Defendant Cyril Willson's Motion to Dismiss Count 5 and Motion to Adopt In-Part Codefendants' Motion to Dismiss Counts 5, 8, 9*, Doc. 394;

The Court's findings and recommendations are set forth *infra*.

A. Factual Background

These charges stem from Defendant USPlabs, LLC's ("USP") sale of dietary/weight loss supplements, which were manufactured by Defendant S.K. Laboratories ("S.K. Labs").[1] Doc. 95 at 5-6. The *First Superseding Indictment* (the "Indictment") generally alleges that Defendants conspired to import and sell synthetic dietary supplements, but falsely marketed the products as plant-based under the theory that federal regulatory agencies would be less likely to question the importation of plant extracts, and retailers would be more likely to sell such products. Doc. 95 at 6. It is alleged that, during the conspiracy, certain Defendants created false documentation to import a synthetic substance, known as DMAA, which they represented was a geranium plant extract; Defendants then used the DMAA in certain of their supplements, which thereafter became bestselling products. Doc. 95 at 7, 14-15.

It is further alleged that when DMAA became the subject of controversy in the dietary supplement industry, USP, through Defendant Jacobo Geissler, began importing other chemicals under false labels to determine if they could be used in new dietary supplements. Doc. 95 at 9. Two such ingredients were aegeline, which is a synthetic version of an extract from a tree native

[1] Defendant USP is a dietary supplement own-label distributor; Defendant S.K. Labs contracted to manufacture USP's supplements and consulted on supplement formulation; Defendants Geissler, Doyle, and Hebert are principals of USP; Defendant Willson is a consultant to USP; Defendant Miles is USP's compliance officer; and Defendant Patel is an employee of S.K. Labs.

to India, and the pulverized roots of a Chinese herb called cynanchum auriculatum ("CA"), both of which USP is alleged to have purchased from China using fake certificates of analysis. The first aegeline-containing version of one of Defendants' supplements was OxyElite Pro "New Formula" ("OEP-NF"). Doc. 95 at 9-10. The second version of the supplement contained both aegeline and CA and was called OxyElite Pro "Advanced Formula" ("OEP-AF"). Doc. 95 at 10.

As alleged in the Indictment, in the fall of 2013, an outbreak of injuries was reported to be associated with USP's aegeline-based products after numerous consumers experienced liver-related symptoms, including liver failure.[2] Doc. 95 at 11. Following an inspection by the Food and Drug Administration ("FDA"), USP agreed to cease distributing the OEP products, but is alleged to have instead pushed sales as fast as possible. Doc. 95 at 11. The Indictment also alleges that USP issued a press release falsely stating that the ingredients in OEP had been researched and showed no negative liver effects, even though Geissler and Defendant Cyril Willson knew that a study had shown such negative side effects. Doc. 95 at 11. Eventually, Geissler instructed that both aegeline and CA be removed from the product going forward. Doc. 95 at 11.

B. The Charges

As relevant here, the Indictment contains the following charges:

Count 1 – *Conspiracy to Commit Wire Fraud*, 18 U.S.C. §§ 1343, 1349; Doc. 95 at 12-17. This count involves certain Defendants' alleged use of false shipping labels, false certificates of analysis ("COAs")[3], and false shipping documentation to support misleading product labeling in

[2] The outbreak occurred in Hawaii.

[3] The FDA defines a COA as "a document, provided by the supplier of a component prior to or upon receipt of the component, that documents certain characteristics and attributes of the component." *Guidance for Industry Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements*, 2010 WL 5574459, at *9 (Dec. 1 2010).

relation to statements that the respective supplements contained "natural" DMAA derived from geranium and CA "extract" (as opposed to CA "root").

Counts 2-5 – *Wire Fraud*, 18 U.S.C. § 1343; Doc. 95 at 18-19. These counts involve certain Defendants' alleged transmission in interstate commerce of false and fraudulent COAs, instructions to create false documents, and other fraudulent statements contained in emails.

Count 6 – *Obstruction of an Agency Proceeding*, 18 U.S.C. §§ 2, 1505; Doc. 95 at 20-21. This count charges that, during the FDA investigation regarding whether an outbreak of liver injuries was associated with USP products containing aegeline, certain Defendants continued to distribute OEP products despite representing to the FDA that they would cease distribution, and attempted to impede the FDA's investigation by failing to provide material information about OEP, the anticipated shipments thereof, and promotional activities therefore.

Count 7 – *Conspiracy to Introduce Misbranded Food Into Interstate Commerce with an Intent to Defraud and Mislead*, 18 U.S.C. § 371; 21 U.S.C. §§ 331(a), 333(a)(2); Doc. 95 at 22-24. This count alleges that certain Defendants conspired to avoid law enforcement attention and match imported substances with false product labeling by instructing Chinese chemical sellers to falsely label numerous chemical powders they sent to USP, including "geranium flower powder extract" and CA root "extract."

Count 8 – *Introduction of Adulterated Food into Interstate Commerce with an Intent to Defraud and Mislead*, 21 U.S.C. §§ 331(a), 333(a)(2); 18 U.S.C. § 2; Doc. 95 at 25. This count alleges that certain Defendants, aided and abetted each other, caused the shipment of OEP-AF in interstate commerce when the label falsely declared that CA "extract" was an ingredient.

Count 9 – *Introduction of Misbranded Food into Interstate Commerce*, 21 U.S.C. §§ 331(a), 333(a)(2); Doc. 95 at 26. This count alleges that certain Defendants caused the shipment of OEP-AF in interstate commerce when the food was misbranded under the Food Drug and Cosmetic Act ("FDCA") in that its label falsely declared that CA "extract" was an ingredient.

Count 10 – *Introduction of Adulterated Dietary Supplement into Interstate Commerce*, 21 U.S.C. §§ 331(a), 333(a)(1); Doc 95 at 27. This count alleges that certain Defendants caused the shipment of OEP-NF in interstate commerce even though the supplement "presented a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling."[4]

[4] The Indictment also alleges in Count 11 that certain Defendants conspired to commit money laundering, but no motion to dismiss has been filed as to that count or as to Count 1. Doc. 95 at 28-29.

C. The Motions to Dismiss

1. *Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Kenneth Miles's Motion to Dismiss Counts Nine and Ten for Unconstitutional Vagueness*, Doc. 221[5]

a. Facial Vagueness of Section 21 U.S.C. § 333

These Defendants first argue that section 333(a)(1) is essentially a strict liability offense and does not require the Government to prove that a defendant acted with an intent to defraud or mislead. Doc. 221 at 9-10. Instead, they note, the Supreme Court has interpreted section 333(a)(1) to allow a defendant to be convicted of an adulteration or misbranding misdemeanor if he "had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, [but] failed to do so." *United States v. Park*, 421 U.S. 658, 673-74 (1975) (also holding that the FDCA does not "make criminal liability turn on 'awareness of some wrongdoing' or 'conscious fraud.'") (quotation marks and citations omitted). Defendants assert that, notwithstanding *Park*, which did not address the constitutionality of section 333(a)(1), Counts 9 and 10 are unconstitutionally vague due to the lack of a scienter requirement. Doc. 221 at 10-11. Additionally, Defendants argue that Defendants Miles, S.K. Labs, and Patel are not executives or control persons of USP, and that neither S.K. Labs nor Patel are even USP employees, and thus cannot be prosecuted for USP's alleged misbranding. Doc. 221 at 13.

The Government responds, *inter alia*, that the FDCA repeatedly has passed constitutional muster because the distribution of food touches people's lives such that they "are largely beyond self-protection." Doc. 240 at 7-8 (citing *Park*, 421 U.S. at 668). Further, the Government points

[5] Counts 9 and 10 are misdemeanor charges.

out that both the Supreme Court and the Court of Appeals for the Fifth Circuit have construed criminal statutes to impose strict liability even where violators could be subject to imprisonment. Doc. 240 at 8-9 (citing, *inter alia*, *United States v. Freed*, 401 U.S. 601, 607-10 (1971); *United States v. Ayo-Gonzalez*, 536 F.2d 652, 661 (5th Cir. 1976)). Additionally, the Government contends that the named Defendants are "responsible corporate agents" properly subject to prosecution because (1) Geissler, Doyle, and Hebert owned and had decision-making authority for USP; (2) Patel supervised the manufacture of USP's products at S.K. Labs; (3) Miles was responsible for ensuring the compliance of USP's products with the FDCA; and (4) the named Defendants directly participated in the formulation, shipment, manufacture, and labeling of the adulterated and misbranded products. Doc. 241 at 9-12. The Government further urges that the relevant statutory provisions are not vague on their face or as applied because the FDCA provides numerous definitions of adulteration and misbranding, which is sufficient to satisfy due process, especially considering the "common sense" meanings that must be given to the FDCA's criminal provisions. Doc. 241 at 12-16.

When a defendant challenges a criminal statute as vague, courts consider the challenge under the rubric of the Fifth Amendment's due process clause. *Johnson v. United States*, 135 S. Ct. 2551, 2556-57 (2015). The government violates due process by taking away an individual's "life, liberty, or property under a criminal law so vague that it fails to give ordinary people fair notice of the conduct it punishes, or so standardless that it invites arbitrary enforcement." *Id*. at 2556 (citation omitted). To qualify as unconstitutionally vague, a statute must be "impermissibly vague in all its applications," *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 495 (1982), including its application to the party bringing the vagueness challenge, *United States v. Clark*, 582 F.3d 607, 612-13 (5th Cir. 2009). "Objections to vagueness under

the Due Process Clause rest on the lack of notice and hence may be overcome in any specific case where reasonable persons would know that their conduct is at risk." *Maynard v. Cartwright*, 486 U.S. 356, 361 (1988). On the other hand, an ordinance is vague in all its applications where (1) "it subjects the exercise of [a] right ... to an unascertainable standard," or (2) persons "of common intelligence must necessarily guess at its meaning." *Coates v. City of Cincinnati*, 402 U.S. 611, 614 (1971) (citation omitted)

Counts 9 and 10 allege violations of 21 U.S.C § 333(a)(1), which makes it a misdemeanor offense to introduce into interstate commerce "any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded," in violation of 21 U.S.C § 331(a). While strict liability crimes are not unheard of and do not always offend constitutional requirements, such offenses are generally disfavored. *United States v. U.S. Gypsum Co.*, 438 U.S. 422, 437-38 (1978). As Defendants argue, section 333(a)(1) does not include a scienter requirement. *See Park*, 421 U.S. at 672-73 ("The [FDCA] does not, as we observed in [*United States v.*] *Dotterweich*, [320 U.S. 277, 281 (1943)] make criminal liability turn on 'awareness of some wrongdoing' or 'conscious fraud.'").

The regulation of food, drugs, and cosmetics pursuant to section 333(a), however, "imposes criminal sanctions as a means of regulating activities so dangerous to the public welfare as not to permit of exception for good faith and ignorance. A person acts at his peril in this field." *United States v. Hohensee*, 243 F.2d 367, 371 (3d Cir. 1957) (citing *Dotterweich*, 320 U.S. 277). Moreover, due process is not violated simply because section 333(a) does not contain a *mens rea* requirement. *See Park*, 421 U.S. at 666 (rejecting appellate court's finding that due process was violated where the defendant was found guilty of violating section 331 despite the lack of evidence of defendant's "wrongful action" given his position of authority in

the corporation); *United States v. Greenbaum*, 138 F.2d 437, (3d Cir. 1943) (holding that due process was not violated merely because *mens rea* was not a required element of the crime of introducing adulterated eggs in interstate commerce because the offense was capable of inflicting widespread injury, and requiring proof of the offender's guilty knowledge and wrongful intent would be virtually impossible) (citing *Shevlin-Carpenter Co. v. Minnesota*, 218 U.S. 57, 69-70 (1910)). Thus, Defendants' motion to dismiss on this basis should be **DENIED**.

b. Vague as Applied

The named Defendants next argue that the statute underlying Count 9 of the Indictment, namely 21 U.S.C. § 343(a)(1), is unconstitutionally vague as applied because they are accused of using "false and misleading" terms by labeling OEP-AF as containing CA "extract" rather than the actual powdered CA root used. Doc. 221 at 14-15. Defendants assert that neither the FDCA nor its regulations define the term "extract," thus the statutory phrase "false or misleading" is unconstitutionally vague as applied to dietary supplements whose labels claim to use "extracts." Doc. 221 at 15.

Defendants assert that Count 10 also must be dismissed because the statute on which the count is based is unconstitutionally vague as applied. Doc. 221 at 16. Defendants particularly take issue with the language in the statute providing that a dietary supplement is "adulterated" if it "presents a *significant* or *unreasonable* risk of illness or injury under conditions of use recommended or suggested in labeling." Doc. 221 at 16 (emphasis added). Defendants contend that the italicized words are irremediably vague and ambiguous. Doc. 221 at 16-18.

With respect to Count 9, the Government responds that the court or a jury can resolve any dispute about the definition of the term "extract," but the use of the word does not make the governing statute vague. Doc. 240 at 14-15. Additionally, the Government avers that the

FDCA's plain language provides ample definitions of the terms "adulterated" and "misbranded" sufficient to satisfy due process, and such provisions must be given their common sense meanings, i.e., it is common sense that potentially dangerous and/or mislabeled supplements are illegal. Doc. 240 at 12. As to Count 10, the Government urges that the term "significant or unreasonable" risk is not vague because jurors make decisions every day using similar standards, and any perceived problem with respect to that language is not addressed by the doctrine of vagueness, but by the requirement that the Government must prove its case beyond a reasonable doubt. Doc. 240 at 13-14.

In Count 9, it is alleged that Defendants misbranded OEP-AF as containing CA "extract" when in fact USP and Geissler substituted an ingredient that cost about six times less. Doc. 240 at 15. As the Government properly observes, substituting a cheaper ingredient for a more expensive one, but listing the more expensive ingredient on the label would constitute misbranding. Moreover, as argued by the Government, simply because there is no statutory or regulatory definition of "extract" does not render the penal statute vague. Indeed, a number of both defense and Government's experts appear to be knowledgeable about what an "extract" is. Government expert Dr. Oberlies appears to have considerable experience in various extraction methods, Doc. 294 at 16-18, and several experts from both sides discuss extracts or rely on extensive scientific literature that discusses extracts, *see, e.g.*, Doc. 222 at 18, 28-29, 65-66, 71-73; Doc. 222-1 at 47; Doc. 222-2 at 7, 19; Doc. 222-3 at 7, 17; Doc. 222-5 at 14; Doc. 222-14 at 11, 29; Doc. 232 at 9, 11, 13, 24-25, 31-32, 39, 59, 65-67. Moreover, juries are capable of using their common sense to determine the core of a meaning that they are capable of understanding. *See Tuilaepa v. California*, 512 U.S. 967, 975 (1994) ("For purposes of vagueness analysis, however, in examining the propositional content of a factor, our concern is that the factor have

some 'common-sense core of meaning . . . that criminal juries should be capable of understanding.'") (quotation omitted); *Mid-Continent Cas. Co. v. Kipp Flores Architects, L.L.C.*, 602 Fed. App'x 985, 994 (5th Cir. 2015) (per curiam) (using a "common sense" approach to determining whether the definition of "advertisement" was met).

Similarly, in Count 10, Defendants are alleged to have shipped adulterated OEP-NF, which the Government claims was associated with an outbreak of severe hepatic injuries. During oral argument, Defendants cited to *Johnson v. United States*, 135 S. Ct. 2551 (2015) and *Sessions v. Dimaya*, 138 S. Ct. 1204 (2018) for the proposition that the phrase "significant or unreasonable risk" is unconstitutionally vague as applied. In *Johnson*, the Court addressed a provision in the Armed Career Criminal Act (the "ACCA"), which enhances a defendant's sentence if, as relevant here, the defendant had three or more convictions for a "violent felony." The ACCA defines "violent felony," in relevant part, as one that "involves conduct that *presents a serious potential risk of physical injury to another*." 135 S. Ct. at 2555-56 (emphasis in original). This came to be known as the "residual clause." *Id.* at 2556.

The *Johnson* Court held that two features of the residual clause rendered it unconstitutionally vague. *Id.* at 2557. First, the residual clause left "grave uncertainty about how to estimate the risk posed by a crime," in that it tied the judicial assessment of risk to an "ordinary case," not to the actual facts of the case or the statutory elements of the violent felony. *Id.* Second, the residual clause left uncertainty about the level of risk it took for a crime to qualify as a violent felony. *Id.* at 2558. The Court concluded that the residual clause's effect of "combining indeterminacy about how to measure the risk posed by a crime with indeterminacy about how much risk it takes for the crime to qualify as a violent felony" rendered it too unpredictable and arbitrary to satisfy the Due Process Clause. *Id.* The Court further noted that

the failure of persistent efforts by courts to establish a workable standard also demonstrated that the residual clause was unconstitutionally vague. *Id.*

Nevertheless, the Court rejected the argument that holding the residual clause unconstitutional would place terms in criminal law such as "substantial risk," "grave risk," and "unreasonable risk" in constitutional doubt. *Id*. at 2561. Distinguishing such terms, the Court noted that they did not generally link themselves with "a confusing list of examples" and, "[m]ore importantly, almost all of the cited laws require gauging the riskiness of conduct in which an individual defendant engages *on a particular occasion*." *Id.* (emphasis in original). The Court thereby pointed out that it did not doubt the constitutionality of laws that called for the application of a standard such as "substantial risk" so long as the phrase related to real-world conduct" rather than an idealized "ordinary case of the crime." *Id.*

In contrast to *Johnson*, the challenged statutory language involved here – "significant or unreasonable risk" – is tied to the actual facts of this case and does not require any assessment about the risk or level thereof presented in a hypothetical scenario. Rather, the language at issue in Count 10 comports with the Supreme Court's statement that such qualitative standards are constitutional when they are tied to "real-world" conduct as is alleged in Count 10. Thus, *Johnson* does not support the dismissal of Count 10.

Dimaya also does not call for a different result. In that case, the Court addressed whether the term "crime of violence" in the Immigration and Nationality Act (the "INA") was unconstitutionally vague. The residual clause provision to which the INA referred provided that a "crime of violence" was "a felony . . . that, by its nature, involves a *substantial risk* that physical force against the person or property of another may be used in the course of committing the offense." 138 S. Ct. at 1211 (emphasis added). As in *Johnson*, in determining whether a

particular felony constituted a crime of violence, courts interpreting the INA were required to assess the underlying crime's "ordinary case" to measure the risk of the crime. *Id.* at 1215. And, as in *Johnson*, the INA also expressed ambiguity about the "level of risk" that would serve to make a crime "violent." *Id.* at 1214-15 (noting the similarity between the ACCA's "serious potential risk" provision and the INA's "substantial risk" language). The *Dimaya* court observed that "[m]any perfectly constitutional statutes use imprecise terms like 'serious potential risk' . . . or 'substantial risk' . . . The problem came from layering such a standard on top of the requisite 'ordinary case' inquiry." *Id.* at 1214. The Court found that the term "substantial" risk, in and of itself, was not vague because jurors made decisions every day using similar standards. *Id.*

In the instant case, the same result holds true in relation to the words "significant or unreasonable" risk as that term is defined in section 21 U.S.C. § 342(f)(1)(A). As such, *Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Kenneth Miles' Motion to Dismiss Counts Nine and Ten for Unconstitutional Vagueness*, Doc. 221, should be **DENIED**.

2. Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, Kenneth Miles, S.K. Laboratories, Inc. and Sitesh Patel's Motion to Dismiss Count 10, Doc. 220

Defendants next assert that the alleged outbreak of liver injuries "associated with" USP's aegeline-containing products cannot support the adulteration charge in Count 10 because the Government fails to set forth sufficient facts, such as scientific testing or expert evidence, that establish a causal connection between the shipment referenced in Count 10 and the purported 2013 outbreak. Doc. 220 at 11-14. Similarly, Defendants argue that the Indictment alleges no facts supporting the alleged risk of illness posed by OEP-NF "under the conditions of use recommended or suggested in the labeling," which is a key element of the crime of adulteration.

Doc. 220 at 14-15 (quoting 21 U.S.C. § 342(f)(1)(A)). Defendants also take issue with the fact that the Indictment does not specify the types of consumers who were allegedly injured by OEP-NF and whether they used the supplement in compliance with the recommended dosage on the label. Doc. 220 at 15-16.[6]

The Government responds that Defendants' motion improperly challenges the sufficiency of the evidence underlying the Indictment when the Court must take all allegations in an indictment as true in considering a motion to dismiss. Doc. 239 at 1-2 (citing *United States v. Fontenot*, 665 F.3d, 640, 644 (5th Cir. 2011)). Moreover, the Government contends that the Indictment adequately charges a crime in Count 10 and gives Defendants sufficient notice of the charge. Doc. 239 at 2-4. As to Defendants' argument that the Indictment must allege facts indicating that consumers used OEP-NF per the terms of the label, the Government asserts that Count 10 contains the required language and greater specificity and supporting evidence is not necessary. Doc. 239 at 4-5.

Pursuant to Rule 7(c) of the Federal Rules of Criminal Procedure: "The indictment or information must be a plain, concise, and definite written statement of the essential facts constituting the offense charged . . . A count may incorporate by reference an allegation made in another count. A count may allege that the means by which the defendant committed the offense are unknown or that the defendant committed it by one or more specified means." As applicable

[6] Defendants also suggest that the Government never undertook any administrative proceedings to declare aegeline or OEP-NF adulterated, which it was "required" to do if it believed that any of USP's products were adulterated. Doc. 220 at 13; Doc. 274 at 9-10. This argument is baseless as there is no such requirement. Additionally, Defendants' argument that the Government has changed the theory of the case as relates to adulteration – to a "mix of ingredients" rather than to solely aegeline − by virtue of the expert reports of Drs. Herbert Bonkovsky and Bill Gurley, Doc. 274 at 5-9, is addressed in the Court's order denying Defendants' motions to exclude those witnesses.

to Count 10, a product shall be deemed to be "adulterated" if it "is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling." 21 U.S.C. § 342(f)(1)(A).

An indictment "in the language of" a criminal statute is valid if the words of the statute "fully, directly, and expressly, without any uncertainty or ambiguity, set forth all the elements necessary to constitute the offence intended to be punished." *Van Liew v. United States*, 321 F.2d 664, 674 (5th Cir. 1963). If, however, as here, the statute is pleaded in the indictment in general terms, "it must be accompanied with such a statement of the facts and circumstances as will inform the accused of the specific offence, coming under the general description, with which he is charged." *Id.* (quoting *Russell v. United States*, 369 U.S. 749, 765 (1962)). "The propriety of granting a motion to dismiss an indictment . . . by pretrial motion is by-and-large contingent upon whether the infirmity in the prosecution is essentially one of law or involves determinations of fact . . . If a question of law is involved, then consideration of the motion is generally proper." *Fontenot*, 665 F.3d at 644 (quoting *United States v. Flores*, 404 F.3d 320, 324 (5th Cir. 2005)). "In reviewing a challenge to an indictment alleging that it fails to state an offense, the court is required to take the allegations of the indictment as true and to determine whether an offense has been stated." *Id.* (quoting *United States v. Crow*, 164 F.3d 229, 234 (5th Cir. 1999)).

Count 10 contains only one substantive paragraph, which states that the named Defendants "shipped and caused the shipment of adulterated [OEP-NF] in interstate commerce . . . [and] [t]he dietary supplement was adulterated because it was a 'dietary supplement . . . that present[ed] a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling." Doc. 95 at 27 (quoting 21 U.S.C.A. § 342(f)(1)(A)). The caption of Count 10 alleges violations of sections 331(a) and 333(a)(1). Doc. 95 at 27.

Nevertheless, Count 10 "incorporates by reference all of the allegations set out in Paragraphs 1 through 35, 39 through 44, and Paragraph 67." Doc. 95 at 27. Those paragraphs set forth (1) the definition of "dietary supplement"; (2) the allegation that Defendants created OEP-NF using the synthetic chemical aegeline; and (3) that, in the fall of 2013, an outbreak of liver injuries was associated with USP's aegeline-containing products, which caused numerous consumers to experience jaundice and other liver-related symptoms and several consumers to need liver transplants. Doc. 95 at 2-3, 9-11.

Here, although the pertinent statutes are pleaded in the Indictment in general terms, they were accompanied by the above description of facts and circumstances, which is sufficient to inform Defendants of the specific offense with which they are charged. FED. R. CRIM. P. 7(c); *Van Liew*, 321 F.2d at 674. Defendants' challenges to Count 10 amount to questions of fact and, thus, are not the proper subject of a motion to dismiss. *Fontenot*, 665 F.3d at 644. Accordingly, D*efendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, Kenneth Miles, S.K. Laboratories, Inc. and Sitesh Patel's Motion to Dismiss Count 10*, Doc. 220, should be **DENIED**.

3. Defendants USPlabs, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motions to Dismiss Counts Two Through Four of the First Superseding Indictment as Untimely, Doc. 293[7]

The Indictment alleges: (1) in Count 2, that Defendants Hebert and Geissler communicated by email in May 2010 regarding fraudulent "geranium" COAs, and a retailer was emailed that DMAA was a natural extract; (2) in Count 3, that Defendants Doyle and Patel

[7] Defendants' opening brief did not list Patel or S.K. Labs in its caption, but it does seek the dismissal of Counts 3 and 4, which involve Patel, an employee of S.K. Labs. Doc. 293 *passim*. Further, although Defendants' reply brief purports to seek dismissal of Counts 2 through 4 as to Miles and Willson, Doc. 344 at 1, Counts 2 through 4 did not involve them.

communicated via email in August 2010 about altering "geranium" COAs to contain false information; and (3) in Count 4, that "Person Y" and Patel discussed in a September 2010 email documents for a shipment of "geranium" for use in USP's products, including the use of a fake COA altered "at co-schemers' direction." Doc. 95 at 19.

Defendants argue that Counts 2 through 4 are untimely because they were not brought within the applicable five-year statute of limitations, and the Government has not established by a preponderance of the evidence that it submitted an official request to China (the "Request") for assistance in its investigation of USP which would be sufficient to toll the limitations period. Doc. 293 at 6. Defendants contend that although Judge Fitzwater signed an *ex parte* order tolling the statute of limitations while China responded to the Request, that order is insufficient to save Counts 2 through 4 from dismissal because: (1) the Government failed to provide to Judge Fitzwater (or to Defendants) a copy of the Request when the Government moved for a tolling order pursuant to 18 U.S.C. § 3292; (2) the Request did not satisfy all the mandatory requirements of the Government's Agreement on Mutual Legal Assistance in Criminal Matters with the People's Republic of China (the "MLAA"); (3) the Government did not demonstrate by a preponderance of the evidence that any evidence supporting Defendants' alleged wrongdoing was actually in China; and (4) there is no evidence of the date that China took "final action" on the Request, which would be the date that tolling ends. Doc. 293 at 6, 9-16. As such, Defendants argue that Judge Fitzwater's tolling order should not be given any effect. Doc. 293 at 10-11, 13.

The Government responds that the statute of limitations was tolled beginning in April 2015 by virtue of its Request, and because China has not yet provided any evidence or taken "final action" in response to the Request, the statute of limitations was tolled pursuant to section

3292, and will continue to be tolled until either (1) China responds; or (2) the expiration of three years, whichever occurs first.[8] Doc. 305 at 1, 8 (citing 18 U.S.C. § 3292(c)). The Government argues that Judge Fitzwater's order was not clearly erroneous since the Government provided Judge Fitzwater with (1) the letter transmitting the Request to China, including the Federal Express receipt, Doc. 293-13; and (2) an affidavit from the Government's attorney verifying that the Request had been sent to Chinese authorities in April 2015, Doc. 293-15. Doc. 305 at 4-5. The Government concludes that its Request need not contain the level of detail set forth in the MLAA because the statute does not require it, nor is it unusual for the Government to maintain the confidentiality of requests for legal assistance from other countries. Doc. 305 at 5-7.

Defendants were first indicted in November 2015. Doc. 1. Counts 2 through 4 are based on emails from 2010, which relate to allegedly falsified geranium COAs. Doc. 95 at 19. The general statute of limitations applicable in non-capital, criminal cases is five years. 18 U.S.C. § 3282(a). Congress, however, has provided for the suspension of the statute of limitations where evidence may be located in a foreign country. 18 U.S.C. § 3292(a)(1). Section 3292 provides that:

> [u]pon application of the United States, filed before return of an indictment, indicating that evidence of an offense is in a foreign country, the district court before which a grand jury is impaneled to investigate the offense shall suspend the running of the statute of limitations for the offense if the court finds by a preponderance of the evidence that an official request has been made for such evidence and that it reasonably appears, or reasonably appeared at the time the request was made, that such evidence is, or was, in such foreign country.

Id.

[8] The three-year period expired in April 2018.

The Government may meet its burden under section 3292 by submitting to the court a variety of documents. *United States v. Trainor*, 376 F.3d 1325, 1332-33 (11th Cir. 2004). The evidentiary requirement is "not a high standard of proof" and may be satisfied by the Government's submission of a broad range of materials, "including a sworn or verified application containing the necessary factual information, testimony by Government officials, affidavits, declarations, exhibits, or other materials of evidentiary value," as well as hearsay evidence, that "meet a minimum threshold of reliability." *Id.* at 1333; *see also United States v. Wilson*, 249 F.3d 366, 371 (5th Cir. 2001) (noting that an application to toll the statute of limitations under section 3292 is a pre-indictment, *ex parte* proceeding, such that only evidence from the government is presented), *abrogated on other grounds by Whitfield v. United States*, 543 U.S. 209, 212 (2005).

As the Government correctly notes, the tolling period begins when the official request is made and ends (1) when the foreign court or authority takes final action on the request, or (2) after three years, whichever period is shorter. 18 U.S.C. §§ 3292(b-c); *United States v. Meador*, 138 F.3d 986, 991-92 (5th Cir. 1998). Section 3292 defines "official request" as "a letter rogatory, a request under a treaty or convention, or any other request for evidence made by a court of the United States or an authority of the United States having criminal law enforcement responsibility, to a court or other authority of a foreign country." 18 U.S.C. § 3292(d).

As argued by Defendants, however, a "request" within the meaning of the MLAA treaty must include:

> (1) the name of the competent authority conducting the investigation to which the request relates;
> (2) a description of the subject matter and nature of the investigation, including the relevant statutes and potential punishments;
> (3) the purpose of the evidence and its relevance to the investigation;

(4) the time limit within which compliance is requested; and
(5) a description of the actual evidence sought.

Doc. 293 at 11 (citing MLAA Art. 4.1); *see also* MLAA Art. 1.3 (providing that the agreement "is intended solely for mutual legal assistance between the Parties. The provisions of this Agreement shall not give rise to a right on the party of any private person to obtain, suppress, or exclude any evidence.").

While a treaty such as the MLAA supersedes a federal statute if there is a conflict, *Medellin v. Texas*, 552 U.S. 491, 518 (2008), there is no direct conflict here. Indeed, this case is analogous to the *Wilson* case cited above. There, the Government presented the district court with only a copy of a letter addressed to the attorney general of the Bahamas, which requested certain authenticated records that allegedly were physically present in the Bahamas. 249 F.3d at 371. The *Wilson* court noted that the official request was made pursuant to an MLAA. *Id*. at n.2 ("The request was made 'pursuant to the Treaty between the United States and the Commonwealth of The Bahamas on Mutual Assistance in Criminal Matters, signed at Nassau June 12 and August 18, 1987' and thus meets 18 U.S.C. § 3292's requirement that the "official request" be "a request under a treaty or convention.")

In the present case, the Government provided to Defendants its 11-page *ex parte Application for an Order Pursuant to 18 U.S.C. § 3292 to Suspend the Limitations Period* (the "Application"), which explained the Government investigation into USP and detailed the roles of a Chinese citizen, Vincent Zhou, and Chinese company, SmartChem, in Defendants' scheme. Doc. 293-12. The Application further included a letter the Government sent to Zhang Xiaoming at the Chinese Department of Judicial Assistance and Foreign Affairs, which explained the nature of the Government's investigation and stated that it sought bank, business, and official

records as well as the opportunity to interview Zhou. Doc. 293-13. The Federal Express mailing label addressed to Xiaoming also was included. Doc. 293-13 at 4. Finally, attached to the Application was a sworn declaration signed by Government attorney Patrick Runkle attesting to the above. Doc. 293-15. The process followed by the Government in this case is substantially the same process described in *Wilson*. Indeed, the Government provided Defendants with more than enough evidence to prove that it submitted the Request. More importantly, the Application and its attachments were sufficient to support Judge Fitzwater's tolling order. Finally, because Defendants have not been provided with the actual Request, their argument that the Government did not wholly comply with the MLAA's requirements for making an official request is speculative. Accordingly, *Defendants USPlabs, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motions to Dismiss Counts Two Through Four of the First Superseding Indictment as Untimely*, Doc. 293, should be **DENIED**. The motion also should be denied as to Patel and S.K. Laboratories for the reasons noted above.

4. Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motion to Dismiss Count Six, Doc. 387

Count 6 charges that, during the FDA's proceedings to determine whether an outbreak of liver injuries was associated with USP's aegeline-based products, these Defendants continued to distribute OEP despite representing to the FDA that they would cease distribution and, in fact, Defendants attempted to impede the FDA's investigation by failing to provide material information about OEP, the anticipated shipments thereof, and promotional activities therefore. Doc. 95 at 20-21 (citing 18 U.S.C. §§ 2, 1505).

a. Failure to State an Offense

Defendants first argue that Count 6 fails to state an offense because the FDA's inspections of USP in October and November 2013 were not "proceedings" within the meaning of 18 U.S.C. § 1505. Doc. 387 at 8-9. The Government counters that the investigations in question qualify as "proceedings before" the FDA. Doc. 411 at 5-13.

Section 1505 imposes criminal liability, in relevant part, upon any individual who "corruptly influences, obstructs, or impedes or endeavors to influence, obstruct or impede the due and proper administration of the law under which any *pending proceeding* is being had *before* any department or agency of the United States. . ." (emphasis added). In *United States v. Pugh*, the Court of Appeals for the Sixth Circuit held that an FDA inspection of an herbal supplement distributor's facilities was an agency "proceeding" for purposes of section 1505. 404 Fed. App'x 21 (6th Cir. 2010). In that case, an FDA inspector appeared unannounced at the company's headquarters and arranged to inspect their warehouses the next day. One of the warehouse managers was told that an investigator was coming, so he moved out of the warehouse boxes which contained mislabeled supplements and, after the investigation was complete, moved the boxes back in. *Id*. at *1. Subsequently, he was convicted of violating section 1505.

On appeal, he argued that the evidence was insufficient because the FDA inspection was not an agency "proceeding" within the meaning of section 1505. *Id*. at *25. The Sixth Circuit rejected this argument, holding that "it is clear . . . that the FDA inspection was an agency proceeding for purposes of the relevant statute." *Id.*; *see also United States v. Senffner*, 280 F.3d 755, 761 (7th Cir. 2002) (holding that an SEC investigation was a proceeding for purposes of section 1505); *United States v. Schwartz*, 924 F.2d 410, 423 (2d Cir. 1991) (holding that a

Customs Service interview of defendants for purposes of determining whether it should seize potentially illegal arms was an "agency proceeding"); *United States v. Vixie*, 532 F.2d 1277, 1278 (9th Cir. 1976) (holding that submitting a false document in response to an IRS subpoena violated section 1505 because the administrative investigation was a "proceeding"); *United States v. Fruchtman*, 421 F.2d 1019, 1021 (6th Cir. 1970) (stating that an investigation conducted by an attorney for the Federal Trade Commission was a "proceeding" under section 1505); *c.f. United States v. Bergfeld*, 280 F.3d 486, 487 (5th Cir. 2002) (noting defendant's guilty plea and conviction under section 1505 for attempting to evade the FDA's prohibition against the importation of certain medical devices, but reversing on speedy trial grounds). Defendants' reliance on *United States v. Ramos* is misplaced because the statute under which that defendant was indicted was 18 U.S.C. § 1512(c), which addresses an "official proceeding" rather than an "agency proceeding." 537 F.3d 439, 462-63 (5th Cir. 2008) (noting the distinction between an "official proceeding" and an agency investigation). Defendants' motion to dismiss on this basis should be denied.

b. Whether Any of Defendants' Alleged Conduct Obstructed or Impeded "the Due and Proper Administration of Law"

i. Whether Defendants' alleged misrepresentation to the FDA that they would cease distributing OEP products constituted an obstruction or impediment

Defendants next argue that none of their alleged conduct "obstructed or impeded" the "due and proper administration of the law" because the actions described in Count 6 "were neither inherently corrupt, nor undertaken for corrupt purposes." Doc. 387 at 12-13. Further, Defendants assert, the FDA had no legal authority to either seize the dietary supplements while on site for the inspection or issue an administrative detention order. Doc. 387 at 15. As such,

Defendants maintain that their alleged sales of OEP products during the FDA's October/November 2013 inspections cannot constitute an act of obstruction or impediment of the "due and proper administration of the law." Doc. 387 at 15-16. Defendants also argue that the FDA did not allege that USP's products were adulterated until the day after the FDA's "proceedings" were completed, so any sales of OEP products during said "proceedings" could not have obstructed or impeded the due and proper administration of the law. Doc. 387 at 16-17.

The Government responds that Defendants' motion to dismiss is procedurally improper because they are essentially challenging the sufficiency of the evidence when the proper issue is whether the Indictment sufficiently charges the offense. Doc. 411 at 10-11, 13. The Government maintains that the Indictment alleges that Defendants falsely told the FDA that they would cease distribution of certain products in an attempt to prevent further potential FDA actions − which constitutes obstruction − and that providing such materially misleading information in the midst of a public health emergency investigation constitutes interference with the "due and proper administration of the law." Doc. 411 at 13-14 (citing Indictment, Doc. 95 at 20). Thus, allegations regarding what the FDA chose to do or not do during the investigations are issues for the jury's consideration. Doc. 411 at 11.

Contrary to Defendants' argument, at this stage of the proceedings, the Government is not required to demonstrate that Defendants' conduct was "corrupt" and, in fact, obstructed or impeded the due and proper administration of the law. *See Mann*, 517 F.2d at 267 (holding that an indictment cannot be dismissed under Rule 12 by virtue of a "sufficiency-of-the-evidence" defense that raises factual questions "embraced in the general issue."). Further, the FDA's ability, *vel non,* to seize or detain the supplements and the issue of when the product was

declared adulterated are simply not material to the issue of whether Count 6 is properly charged. As such, Defendants' motion to dismiss Count 6 on that basis should be denied.

ii. Whether Defendants' actions constituted an obstruction or impediment to the proceedings

Defendants next argue that the allegation that they attempted to obstruct and impede the FDA's investigation by failing to provide material information about OEP, anticipated shipments thereof, and related promotional activities must be dismissed because they had no affirmative duty to provide the FDA with any more information than what the agency was authorized to obtain. Doc. 387 at 17-18. Defendants assert that the FDA's authority to demand information during an inspection is limited by specific grants of statutory authority, and Defendants' alleged omission of information is not a criminal act because they had no duty to disclose. Doc. 387 at 18-19. The Government counters that omissions in providing information violate the obstruction statute because they block the flow of truthful information. Doc. 411 at 15.

The Indictment alleges that Defendants attempted to impede the FDA's investigation by representing that they would cease and desist distribution of OEP products, but then continuing to sell the products and "failed to provide material information about [OEP], the anticipated shipments thereof, and the promotional activities therefor." Doc. 95 at 20-21. The allegations are sufficient to put Defendants on notice of the specific conduct that allegedly violated section 1505, which is the salient issue. The determination of whether such allegations, if proven, establish Defendants' corrupt obstruction or impediment, is an issue reserved to the trier of fact. *See United States v. Rainey*, 757 F.3d 234, 247 (5th Cir. 2014) (holding that an indictment must allege every element of the crime charged and in such a way as to enable the accused to prepare his defense and allow the accused to invoke the double jeopardy clause in any subsequent

proceeding, but noting that the Court "is not concerned with whether the indictment could have been better framed, or whether it invokes a particular 'ritual of words' . . . so long as the indictment as a whole 'fairly imports' the element."). Accordingly, *Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motion to Dismiss Count Six*, Doc. 387, should be **DENIED**.

5. Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Sitesh Patel, and Cyril Willson's Joint Motion to Dismiss Count 7, Doc. 379

Count 7 of the Indictment charges the named Defendants with Conspiracy to Introduce Misbranded Food Into Interstate Commerce with an Intent to Defraud and Mislead in violation of 21 U.S.C. §§ 331(a), 343(a)(1). Doc. 95 at 22-24. The Indictment alleges that the object of the conspiracy was to avoid law enforcement attention and match imported substances with false and misleading product labeling, and that overt acts committed in furtherance of that object included instructing Chinese chemical sellers to falsely label packages sent to USP, to wit: labeling DMAA as "geranium flower powder extract," labeling nine different chemicals as "green coffee samples" in individual bags, and labeling ground CA root powder as CA root "extract."

Defendants assert that Count 7 should be dismissed because (1) the documents at issue in this count – written materials accompanying the importation of the food to S.K. Labs and USP from China – do not fall within the definition of "labeling"; (2) the Indictment does not allege facts establishing that the allegedly false and misleading "labeling" was material; and (3) the FDCA's definition of "labeling" is unconstitutionally vague. Doc. 379 at 1.

Defendants first argue that the term "labeling" only applies to materials that provide information about the product to the prospective purchasers and ultimate consumers whom the FDCA is designed to protect. Doc. 379 at 7-9. They contend that they did not violate the statute because the documents supporting Count 7 were not directed to the ultimate consumer – they were directed to USP and S.K. Labs. Doc. 379 at 10-11. Further, Defendants argue, the written materials at issue did not constitute labels that were intended to "provide substantial information about the use or benefits of the article" to the consumer as required. Doc. 379 at 10 (quoting *United States v. Hanafy*, 124 F. Supp. 2d 1016, 1027 (N.D. Tex. 2000)).

The Government responds that a "food shall be deemed to be misbranded" in violation of 21 U.S.C. § 343(a)(1), "[i]f [] its labeling is false or misleading in any particular." Doc. 404 at 6 (quoting 21 U.S.C. § 343(a)(1)). Further, "labeling" includes "labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Doc. 404 at 6 (quoting 21 U.S.C. § 321(m)). Accordingly, the Government asserts that the statute plainly encompasses written materials accompanying food ingredients; thus, the "food" Defendants caused to be shipped had false "labeling" in violation of section 343(a)(1). Doc. 404 at 6-7. Further, the Government adds that the basic identity of the substances being shipped and their provenance are "substantial information" to government regulators and others about the articles and, as such, they constitute "labeling" under 21 U.S.C. § 321(m). Doc. 404 at 9. Finally, the Government contends that the Indictment satisfies even Defendants' incorrect assertion that the labeling must be directed to the end user because "the conspiracy propagated false labeling from ingredient shipments to false and misleading labeling of end products to consumers and retailers." Doc. 404 at 10.

Defendants reply that the Government is changing its theory of the case by focusing on consumers' exposure to allegedly misbranded finished products rather than, as the Indictment specifies, Defendants' alleged attempt to mislead the FDA regarding the ingredients used in the supplements. Doc. 437 at 3-4. Defendants assert that the only "consumer" of the ingredients at issue was USP, which knew what they were. Doc. 437 at 3.

The purpose of the FDCA is "to safeguard the consumer by applying [it] to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer." *United States v. Sullivan*, 332 U.S. 689, 696 (1948). The Indictment alleges that the false documentation that accompanied the shipments of the supplement ingredients constituted labels. Doc. 95 at 23-24. Section 321(m) plainly states that the term "labeling" includes "all labels and *other written, printed, or graphic matter* (1) upon any article or any of its containers or wrappers, or (2) *accompanying such article*." 21 U.S.C. § 321(m) (emphasis added). Thus, putting aside the definition of the term "label," section 321 also prohibits "other [false] written, printed, or graphic matter" from accompanying food "articles." Count 7 alleges that falsified documents accompanied the three shipments in question. Such documentation is "labeling" within the meaning of the FDCA.

Nevertheless, the documentation also must "provide substantial information about the use or benefits of the article," *United States v. Hanafy*, 302 F.3d 485, 490 (5th Cir. 2002), and thereby constitute "an essential supplement to the label attached to the package," *Kordel v. United States*, 335 U.S. 345, 348 (1948). In that light, the *Hanafy* court held that documentation which merely identified the contents of a shipping tray with no more information than that which was already on the articles themselves did not "explain" or provide "substantial information" rising to the level of "labeling." 302 F.3d at 490. While the Government argues that the labels

accompanying the food articles at issue constituted "substantial information" to government regulators about the articles, there is no suggestion in the record that the allegedly substantial information explained the use of or benefits of the article as required by *Hanafy* or that Defendants conspired to have it do so.

Rather, it appears from the language of Count 7 that the "labeling" in question constituted Defendants' identifying the articles sent "with no more information than that which [was] already upon the articles themselves." Merely putting a "label" on something – albeit an allegedly false label – that does not "explain" or provide "substantial information" is insufficient and does not rise to the level of "labeling" as contemplated by *Kordel* and *Hanafy*.

Thus, Defendants' motion to dismiss Count 7, Doc. 379, should be **GRANTED** on this basis.

6. Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Kenneth Miles' Joint Motion to Dismiss Counts 5, 8, and 9, Doc. 383

Counts 5, 8, and 9 are premised entirely on the sale of OEP-AF, which allegedly contained CA root as opposed to CA extract. Count 5 charges Defendants Doyle and Willson with wire fraud, 18 U.S.C. § 1343, based on an email communication from August 2013 between the two regarding a "draft product advertisement featuring false claims about [CA] (root) extract that were ultimately included on USP's website." Doc. 95 at 19. Defendants USP and Geissler are charged in Count 8 with felony misbranding, 21 U.S.C. §§ 331(a), 333(a)(2). Defendants Doyle, Hebert, S.K. Labs, Patel, and Miles are charged in Count 9 with misdemeanor misbranding, 21 U.S.C. §§ 331(a), 333(a)(1). Doc. 95 at 25-26. The latter two charges are based on an October 2013 shipment of OEP-AF with a label that falsely declared CA root extract as an ingredient in the product.

Defendants move to dismiss the respective counts against them pursuant to Rule 12(b)(3)(B)(v) of the Federal Rules of Criminal Procedure for failure to state an offense. Doc. 383 at 1. They argue that Counts 5, 8, and 9 fail to establish that the identification of CA as an "extract" on OEP-AF's label and related advertisements is false and misleading. Doc. 383 at 3. Defendants assert that, according to the dictionary definition of the term "extract," the CA root utilized in OEP-AF is in fact an extract because Defendant Geissler stated that it was "washed with water to remove fibers and sh-t." Doc. 383 at 5 (defining "extract" per Merriam Webster's Dictionary as "a product (such as an essence or concentrate) prepared by extracting; especially: a solution (as in alcohol) of essential constituents of a complex material (such as meat or an aromatic plant)." Defendants further note that the dictionary definition of extract also means "to withdraw (something, such as a juice or a constituent element) by physical or chemical process." *Id*. (quoting MERRIAM WEBSTER'S DICT.) (online ed. 2017)). Defendants claim that under these definitions, the form of CA used in OEP-AF was an "extract," even as pulverized powder, because the process described by Defendant Geissler "withdrew" a portion of the root from fibers and other materials contained in the root "by a physical . . . process," prior to converting the substance into powder. Doc. 383 at 5-6. In the alternative, Defendants argue that Count 5 should be dismissed because the Indictment does not allege facts sufficient to establish that the alleged "extract" misrepresentation was material to consumers or that CA powder does not confer the same benefits as CA extract. Doc. 383 at 6-7.

The Government responds that the issue of whether the ingredient in OEP-AF was an extract is a question for the jury. Doc. 407 at 3-4. The Government points out that the Indictment, which is valid on its face, alleges that pulverized root of CA is not the same as CA extract, and the allegations in the Indictment must be taken as true in addressing a motion to

dismiss. Doc. 407 at 3-4. As for the materiality of Defendants' representations specifically in relation to Count 5, the Government urges that the Indictment's alleged facts permit an inference of materiality and, that too, is a question for the fact-finder. Doc. 407 at 4-5.

a. CA Root as an Extract

As the Government correctly asserts, on a motion to dismiss an indictment, the Court must take all allegations in the indictment as true. *Fontenot*, 665 F.3d at 644. Hence, an indictment cannot be dismissed under Rule 12 by virtue of a "sufficiency-of-the-evidence" defense that raises factual questions "embraced in the general issue." *Mann*, 517 F.2d at 267 (quotation omitted). With respect to the parties' assertions about the nature of the CA, albeit powder or extract, those are questions of fact for the jury as the Government correctly argues. *See Sparf v. United States*, 156 U.S. 51, 78-79 (1895) ("It is the province of the court, and of the court alone, to determine all questions of law arising in the progress of a trial; and it is the province of the jury to pass upon the evidence, and determine all contested questions of fact.); *see, e.g.*, *United States v Dixon*, 132 F.3d 192, 298 (5th Cir. 1997) (finding that question of whether defendant's sale of drugs was an act in furtherance of a drug conspiracy as charged, rather than an independent drug sale, was a question of fact for the jury); *United States v. Hancock*, 268 F.2d 205, 206 (2d Cir. 1959) (in prosecution for wire fraud, questions about whether defendant had made a false representation as to a borrower's assets in interstate telephone conversation for purpose of inducing loan and whether the lender relied thereon were for jury). Thus, Defendants' motion to dismiss Counts 5, 8, and 9 on this basis fails.

b. Materiality of the "Extract" Misrepresentation in Regard to Count 5

Materiality of a falsehood is an element of the wire fraud statute and is also a question for the jury. *Neder v. United States*, 527 U.S. 1, 9, 25 (1999). If the facts alleged in an indictment

warrant an inference of materiality, the indictment is not fatally insufficient for its failure to allege materiality verbatim. *United States v. Caldwell*, 302 F.3d 399, 409 (5th Cir. 2002). The Indictment here makes several allegations that pertain to the materiality element of Count 5. Among other things, the Indictment alleges that Defendants created and used a promotional write-up for OEP-AF that touted "ethanol extracts" of the CA root as among the "hard-hitting super extracts" in the product. Doc. 95 at 16. Defendants stated that these extracts had produced "exciting emerging data" in scientific studies when, as alleged in the Indictment, the extract Defendants advertised was not in the product. Doc. 95 at 16. Defendants admit in their motion that OEP-AF contained no ethanol extract of CA (they claim it was a "water" extract). Doc. 383 at 5-6. They also admit that the advertising text as alleged in the Indictment appeared on their website. Doc. 383 at 6. These allegations are sufficient to infer materiality because, if true, Defendants falsely stated in advertising that their dietary supplement contained a "hard-hitting" extract that had produced "exciting emerging [scientific] data." Further, if proven, it is also apparent that Defendants made these misrepresentations to convince consumers to buy their product. It is inarguable that consumers purchase dietary supplements, in part, based on their purported ingredients and the supposed effects of those ingredients. Thus, Defendants' alleged statements about what their supplements contained are material to those buying decisions.

Accordingly, *Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Kenneth Miles' Joint Motion to Dismiss Counts 5, 8, and 9*, Doc. 383, should be **DENIED**.

7. Defendant Kenneth Miles' Motion to Dismiss Counts 9 and 10, Doc. 392

In addition to adopting the arguments raised in the prior motions to dismiss Counts 9 and 10, Doc. 220 & Doc. 221, Defendant Miles separately moves to dismiss these counts on the basis

that (1) he is not a "responsible corporate officer"; and (2) it was "objectively impossible" for him to prevent the alleged violations. Doc. 392 at 1, 4-8.

Miles alleges that he was hired by USP in June 2012 – years after the alleged conspiracies began − as a salaried employee for the position of Chief Compliance Officer and he was not the "quality assurance executive" the Indictment describes. Doc. 392 at 5-6 (arguing that the quality assurance executive was Lorena Macias). Miles contends that his role at USP was to improve its "Good Manufacturing Procedures" in compliance with the FDA regulations. Doc. 392 at 5-6. In doing so, Miles alleges that he necessarily relied on representations from USP's owners, his fellow employees, legal counsel, and independent auditors. Doc. 392 at 5. As such, Miles argues that he did not have the power or authority to take necessary measures to prevent or remedy the alleged violations of the FDCA statute nor was he privy to the emails, falsified documents, or communications which the Government claims as proof of intent to defraud and mislead in Counts 9 and 10. Doc. 392 at 5-8. Further, Miles contends that he was completely unaware that OEP was causing "liver issues" or that the other Defendants were hiding that information. Doc. 392 at 8.

Again, the Government maintains that (1) the Indictment sufficiently charges Miles as being responsible for FDCA compliance and shipping and causing the shipment of products in violation of the FDCA; and (2) Miles' arguments that he had no such responsibility and could not have prevented the criminal acts are factual disputes that can only be resolved by a jury. Doc. 415 at 2-6.

For the reasons already stated, the Government is correct that Miles' challenges to the indictment are fact-based and must be reserved for the jury. *Fontenot*, 665 F.3d at 644; *Mann*,

517 F.2d at 267. Accordingly, Miles' *Motion to Dismiss Counts 9 and 10*, Doc. 392, should be **DENIED**.

8. Defendant Cyril Willson's Motion to Dismiss Count 5 and Motion to Adopt In-Part Codefendants' Motion to Dismiss Counts 5, 8, 9, Doc. 394

The Indictment alleges that Willson was "responsible for coordinating much of USP's scientific research and for identifying new substances as prospective ingredients." Doc. 95 at 2. Count 5 charges Defendants Doyle and Willson with wire fraud, 18 U.S.C. § 1343, based on an email communication from August 2013 between the two regarding a "draft product advertisement featuring false claims about [CA] (root) extract that were ultimately included on USP's website." Doc. 95 at 19.

In addition to moving to adopt the arguments raised in the prior motion to dismiss Count 5, Doc. 383, Willson separately moves to dismiss this sole count against him. He first argues that the allegations and undisputed facts establish that the ingredient at issue was an extract, or at least that Willson believed it to be, so he cannot be properly alleged to have made or intended to make a false representation. Doc. 394 at 1-2. Additionally, Willson asserts that the Indictment's allegations are vague because they do not explain what an "extract" is. Doc. 394 at 4-6.

The Government responds that the pulverized root powder that Defendants used in their product is not the same as an "extract," which contains only compounds extracted by a solvent. Doc. 416 at 2-3. And again, the Government maintains that the Indictment sufficiently charges Willson, and he cannot raise factual disputes (despite framing the facts as "undisputed") in a motion to dismiss. Doc. 416 at 3-5.

Willson's request to adopt, in relevant part, the arguments raised by Codefendants in Doc. 383 is **GRANTED**. However, for the reasons already stated, the Government is correct

that Willson's challenges to the indictment are fact-based and must be reserved for the jury. *Fontenot*, 665 F.3d at 644; *Mann*, 517 F.2d at 267. As such, Willson's motion to dismiss Count 5, Doc. 394, should be **DENIED**.

C. CONCLUSION

For the reasons stated above, it is recommended that:

1. *Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel, and Kenneth Miles's Motion to Dismiss Counts Nine and Ten for Unconstitutional Vagueness*, Doc. 221, be **DENIED**;

2. *Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, Matthew Hebert, Kenneth Miles, S.K. Laboratories, Inc., and Sitesh Patel's Motion to Dismiss Count Ten*, Doc. 220, be **DENIED**;

3. *Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motion to Dismiss Counts Two Through Four of the First Superseding Indictment as Untimely*, Doc. 293, be **DENIED**;

4. *Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel and Cyril Willson's Motion to Dismiss Count 7*, Doc. 379, be **GRANTED**;

5. *Defendants USPlabs, LLC, Jacobo Geissler, Jonathan Doyle, Matthew Hebert, S.K. Laboratories, Inc., Sitesh Patel and Kenneth Miles' Joint Motion to Dismiss Counts 5, 8, and 9*, Doc. 383, should be **DENIED**;

6. *Defendants USPlabs, LLC, Jonathan Doyle, Jacobo Geissler, and Matthew Hebert's Motion to Dismiss Count 6*, Doc. 387, be **DENIED**;

7. *Defendant Kenneth Miles' Motion to Dismiss Count Nine and Ten*, Doc. 392, be **DENIED**; and

8. *Defendant Cyril Willson's Motion to Dismiss Count* 5, Doc. 394, be **DENIED**.

SO RECOMMENDED on June 13, 2018.

RENEE HARRIS TOLIVER
UNITED STATES MAGISTRATE JUDGE

INSTRUCTIONS FOR SERVICE AND
NOTICE OF RIGHT TO APPEAL/OBJECT

A copy of this report and recommendation will be served on all parties in the manner provided by law. Any party who objects to any part of this report and recommendation must file specific written objections within 14 days after being served with a copy. *See* 28 U.S.C. § 636(b)(1); FED. R. CIV. P. 72(b). An objection must identify the specific finding or recommendation to which objection is made, state the basis for the objection, and specify the place in the magistrate judge's report and recommendation where the disputed determination is found. An objection that merely incorporates by reference or refers to the briefing before the magistrate judge is not specific. Failure to file specific written objections will bar the aggrieved party from appealing the factual findings and legal conclusions of the magistrate judge that are accepted or adopted by the district court, except upon grounds of plain error. *See Douglass v. United Services Automobile Ass'n,* 79 F.3d 1415, 1417 (5th Cir. 1996), *modified by statute,* 28 U.S.C. § 636(b)(1) (extending the time to file objections from ten to fourteen days).

RENÉE HARRIS TOLIVER
UNITED STATES MAGISTRATE JUDGE